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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,187	02/04/2002	John Walter Liebeschuetz	00219/US	8364

24330 7590 06/20/2003

Martin A. Hay
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Macclesfield Cheshire UK, SK11 6LP
UNITED KINGDOM

EXAMINER

HABTE, KAHSAI

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/20/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,187

Applicant(s)

LIEBESCHUETZ ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34 and 35 is/are allowed.
- 6) ☒ Claim(s) 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 34-36 are pending.

Abstract

2. The abstract is defective because there are no definitions for variables for R2, X, Y, Cy and L. It is required that applicants define these variables or draw the chemical structure of the elected species (Example 48) in the abstract.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 36, there has been recited a method of treating a thrombotic disorder in general, but the specification is not enabled for such a scope.

Thrombosis is an obstruction of an artery or vein by a blood clot (thrombus). Arterial thrombosis is generally more serious because the supply of oxygen and nutrition to an

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area of the body is halted. Thrombosis of one of the arteries leading to the heart (heart attack; see infarction) or of the brain (stroke) can result in death and, in a vessel of the extremities, may be followed by gangrene. Acute arterial thrombosis often results from the deposition of atherosclerotic material in the wall of an artery, which gradually narrows the channel, precipitating clot formation. A thrombus that breaks off and circulates through the bloodstream is called an embolus. Infarction is a blockage of blood circulation to a localized area or organ of the body resulting in tissue death. Infarctions commonly occur in the spleen, kidney, lungs, brain, and heart. The acute emergency known as myocardial infarction, or heart attack, is usually caused by a blockage in one of the coronary arteries that supply blood to the heart muscle. The blockage typically occurs when a blood clot (see thrombosis) lodges in an area already narrowed by arteriosclerosis; other causes are vasospasms in the arterial walls or viral infection of the heart. Symptoms include a crushing pain in the chest radiated to either arm (more commonly the left arm), the jaw, and the neck, although in some cases there are no symptoms at all. The seriousness of the infarction is dependent upon the amount of heart muscle affected, how long the area is deprived of blood, and whether it affects the natural pacemaker of the heart, setting off arrhythmias such as ventricular fibrillation. Death of heart muscle tissue and heart failure may result (see congestive heart failure); damage to other vital organs, including the brain, may occur if the heart is unable to pump necessary oxygen and blood to them.

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Hemophilia is a genetic disease in which the clotting ability of the blood is impaired and excessive bleeding results. The disease is transmitted through females but almost invariably affects male offspring only. A male born to a carrier mother has a 50% chance of having the disease. A hemophiliac cannot pass the disease to his sons, but all his daughters will be carriers. There are two diseases usually classified as hemophilia: hemophilia A (classical hemophilia, or Factor VIII deficiency) and hemophilia B (Christmas disease, or Factor IX deficiency). Small wounds and punctures are usually not a problem for hemophiliacs and can be treated as in a nonhemophiliac. Uncontrolled internal bleeding, however, can result in pain and swelling and permanent damage, especially to joints and muscles. The symptoms often first appear in toddlers as their joints begin to bear weight.

Other thrombotic disorders include:

- Arterial embolism
- Pulmonary embolism
- Deep venous thrombosis
- Renal vein thrombosis
- Atheroembolic renal disease
- Thrombophlebitis
- Stroke
- Heart attack
- Angina

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Thrombotic disorder as shown above covers both too little (e.g. hemophilia A or B) or too much of clotting (e.g. arterial embolism). According to the specification (page 1), serine protease inhibitors play a central role in the regulation of coagulation. On page 2 of the specification, it has been disclosed that inhibitors Factor Xa have value as a therapeutic agent as anticoagulant and are potential useful in the treatment of thrombotic disorders such as venous thrombosis, pulmonary embolism, arterial thrombosis, myocardial ischaemia, myocardial infarction, and cerebral thrombosis. Thus, the claimed compounds would have adverse effect for the treatment of Hemophilia. Since thrombotic disorders are extremely diverse and include too much and too little of thrombosis, an enablement rejection is proper.

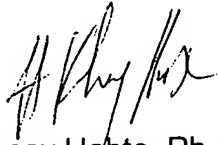
Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

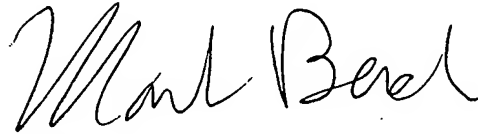
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Kahsay Habte, Ph. D.
Examiner
Art Unit 1624



Mark L. Berch
Primary Examiner
Art Unit 1624

KH
June 19, 2003